DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

CA-GUARD, LTD.
Mr. Al Weisenborn
Official Correspondent
19526 East Lake Drive
Miami, FL 33015

JUL 27 2015

Re: K020614
Trade/Device Name: Irrigating Cannula
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX, GCJ
Dated (Date on orig SE ltr): February 21, 2002
Received (Date on orig SE ltr): February 25, 2002

Dear Mr. Weisenborn,

This letter corrects our substantially equivalent letter of May 24, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): K020614

Device Name: Irrigating Cannula

Indications for Use:

The CA-Guard Irrigating Cannula is intended to provide an access port to body cavities for endoscopes and endoscopic accessories when intraoperative irrigation or infusion of trocar wound surfaces is desired.

David A. Segmm

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020614

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Summary of Safety and Effectiveness for the Irrigating Cannula

Submitted by
CA-Guard, LTD.
610 E. Olympia Ave
Punta Gorda, FL 33950
Phone: (941) 833-1102

Contact Person: Al Weisenborn
Device Trade Name: Irrigating Cannula
Common Name: Cannula
Classification Name: Endoscopes and Accessories, per 21 CFR §876.1500

Identification of a Legally Marketed Predicate Device

The Irrigating Cannula is substantially equivalent to the cannula manufactured and marketed by the United States Surgical Corporation as part of the Versaport® Trocar System pursuant to 510(k) K954108.

General Description

The Irrigating Cannula is a non-toxic, sterile, single use, disposable surgical access port. The device is intended to be inserted percutaneously into the peritoneal cavity to provide access for endoscopic instruments. The cannula is intended to replace the cannula that is supplied with the United States Surgical Versaport® 11mm Trocar System.

The proximal end of the cannula is equipped with a female luer connector. The luer communicates with 6 longitudinal grooves on the surface of the inner member of the cannula. The inner member is covered with polyolefin shrink tubing. An array of twenty-four (24) holes deliver infusate to the compromised tissue surfaces of the trocar wound.

Intended Use

The CA-Guard Irrigating Cannula is intended to provide an access port to body cavities for endoscopes and endoscopic accessories when intraoperative irrigation or infusion of trocar wound surfaces is desired. The cannula has been tested for compatibility with lidocaine and marcane. Saline and water may also be used as irrigants. The CA-Guard Irrigating Cannula is inherently a needleless system and therefore, minimizes the possibility of "needle sticks" for healthcare workers, in accordance with the Needlestick Safety and Prevention Act of 2000.

The CA Guard Irrigating Cannula is designed to be mechanically compatible with all components of the United States Surgical Versaport® 11mm Trocar System using the 5 mm PLUS SEAL.

Summary of Technological Characteristics

The Irrigating Cannula was compared to the predicate device using 14 points of comparison and found to be equivalent.

Summary of Performance Data

Performance of the device was characcterized and compared to that of the predicate utilizing 5 tests. Additionally, the cannula was tested for compatibility with the indicated infusates. The tests demonstrated the Irrigating Cannula is substantially equivalent to the cannula manufactured and marketed by the United States Surgical Corporation as part of the Versaport® Trocar System pursuant to 510(k) K954108. The materials of construction have been carefully selected for their long history of biocompatibility.

Since the Irrigating Cannula embodies technological characteristics essentially identical to those of the predicate device, we believe the device is safe and effective and that it performs as well as or better than the predicate device. The device has been designed and developed utilizing design control methods in compliance with the QSR. The Irrigating Cannula will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.